

Hendricks is not being punished or picked on, without further clarification by the Great Eastern IACUC, he may have a valid classification question worth considering.

Let's assume the few animals in question experienced unrelieved pain longer than "momentary" or greater than "minor." Do any laws, policies or instructions indicate that we should report such animals in category E? The answer is maybe. Unfortunately, the policies and instructions explaining how to classify animals into column E are not found in one single document. Additionally, policies and instructions are revised sporadically for clarification. The reporting requirement for USDA-covered species originates in the Animal Welfare Act (AWA), section 2.36 (ref. 1). The wording in the AWA is very similar to that found on APHIS Form 7023, used by research facilities for their yearly report. Later, Policy 17 was written to further clarify annual reporting². Policy 17, as originally written or later revised, did not tinker with what seems to be a clear identification of which animals should be included in column E of Form 7023. To my knowledge, there are no other specific instructions originating from the USDA regarding annual reports. Considering the tenor of the regulations above, I can understand Hendricks' position.

The wording in the AWA and on Form 7023 seems to emphasize that the classification of animals in column E revolves around pain or distress, where the use of drugs to relieve pain would interfere with the research. For research institutions, the classification takes the form of a prospective question on a protocol. Retrospectively, an institution may find procedures for which no drug or therapy eliminates pain or distress; animals undergoing such procedures would also be included in column E. The animals at Great Eastern fall into neither category, and interference with research was not the issue in the current scenario. The pain was recognized, albeit late, and rectified. Notably, within the Office of Animal Care and Use (NIH-ARAC Guidelines³), clear instructions are provided for filling out APHIS Form 7023. These guidelines specifically indicate that the animals in question should be included in column E of the annual report. I wonder if these guidelines are strictly internal policy or if they constitute common, albeit unwritten, knowledge.

A word from OLAW and USDA

In response to the issues raised in this scenario, the Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offer the following clarification and guidance:

The requirement for submission of an annual report of research facilities, finalized in 1971 (ref. 1), was enacted in order to collect information necessary for USDA to fulfill its responsibilities under the Animal Welfare Act—that is, to show that research facilities were following professionally acceptable standards governing care, treatment and use of animals. Research facilities are required to report the number of animals used in experiments without pain or distress; the number of animals used in experiments involving pain or distress for which pain-relieving drugs were used; and the number of animals used in experiments involving pain or distress for which pain-relieving drugs were not used. Routine procedures (e.g., injections, tattooing, blood sampling) involving some necessary pain and distress need not be reported because the pain and discomfort involved in such procedures are of a transient nature².

In July 2000, USDA published a request for comments, recognizing that the current system does not include a means to report certain situations, such as the one described in this scenario, where animals experience pain or distress for a reason other than that the use of anesthetic, analgesic or tranquilizing drugs would have adversely affected the procedures, results, experiments, surgery or tests³.

Guidance on how to report this type of situation may be found in the *Research Facility Inspection Guide*⁴, on page 14.1.3. An animal that experiences an unexpectedly high level of pain due to the research procedures during a study, where the pain is recognized and appropriately treated, may be reported in Column D. Of greater concern is the training issue regarding timely reporting to the attending veterinarian of problems concerning animal health and well-being; as mentioned by the respondents, this needs to be resolved. Failure to monitor animals post-procedurally to ensure well-being and to promptly notify the veterinarian that animals were experiencing postoperative pain constitutes a serious departure from provisions of the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*⁵. In PHS-supported animal studies, the PHS *Policy (IV.F.3.a.)* requires institutions to report such incidents and to provide a plan and schedule to prevent their recurrence⁵.

1. US Department of Agriculture. Animal and Plant Health Service. 9 CFR Part 2: Animal Welfare Regulations; Final Rule. *Federal Register* **36**, 24917–24928 (1971).
2. US Department of Agriculture. Animal and Plant Health Service. 9 CFR Part 2: Animal Welfare Regulations; Final Rule. *Federal Register* **42**, 31022–31029 (1977).
3. US Department of Agriculture. Animal and Plant Health Service. 9 CFR Part 2: Animal Welfare Regulations; Request for Comments. *Federal Register* **65**, 42304–42305 (2000).
4. US Department of Agriculture. *Animal Care Resource Guide: Research Facility Inspection Guide* (US Department of Agriculture, Washington, DC, 2001). <http://www.aphis.usda.gov/animal_welfare/rig.shtml>
5. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

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In my opinion, the animals should be left in column D. If Great Eastern has a policy covering the current scenario, that policy should be given to Hendricks. Otherwise, Great Eastern should consider its response at a convened meeting of the IACUC. I would welcome further commentary from the USDA.

1. Animal Welfare Act. 9 CFR Ch.1, 2.36.
2. United States Department of Agriculture. *Animal Care Policy Manual* (USDA, Beltsville, MD, 1997). <http://www.aphis.usda.gov/animal_welfare/policy.shtml>
3. Office of Animal Care and Use. *ARAC Guidelines*. <<http://oacu.od.nih.gov/ARAC/index.htm>>

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